April 17, 2006

Preston Black
Director
Office of Legal Affairs
Indiana State Department of Health

Dear Mr. Black:

Pursuant to IC 4-22-2-28, the Indiana Economic Development Corporation ("IEDC") has reviewed the economic impact analysis associated with the proposed Rule affecting 410 IAC 15-2.4, 410 IAC 26, and 410 IAC 27 proposed by the Indiana State Department of Health (ISDH). The proposed rule requires ambulatory surgery centers, abortion clinics, and birthing centers to have a serious adverse event reporting system in place for events that occur on or after January 1, 2006 and requires reports of serious adverse events to be submitted to the ISDH not later than fifteen (15) days after the serious adverse event occurs. Data submission will occur online in real time utilizing the existing ISDH electronic portal. Facilities must review the serious adverse events through their quality assessment and improvement program. The ISDH is required to analyze and publish the data no less than annually.

The fiscal impact to affected entities associated with this rule consists of initial expenses to implement the program as well as recurring expenses for facilities in which serious adverse events occur. The ISDH anticipates that the total number of small businesses affected by the rules changes is approximately 44. The total estimated employee compensated time per hospital for initial start-up compliance during the first year is twenty (20) labor hours. The ISDH expects these activities to be coordinated and performed by middle managers. The estimated total start-up expense based on estimated labor rates is $500 [20 hours x $25/hour].

Facilities in which serious adverse events occur would experience administrative costs associated with complying with the rule. The time required for gathering the information, determining whether reportable, and filing the report is likely no more than two (2) hours per event. At a rate of one reportable incident per month, the estimated compliance hours incurred by providers per year would be twenty-four (24) hours per year. For facilities with few or no reportable errors, the cost is proportionately lower. Facilities reporting a significant number of errors would incur costs proportionately higher. The estimated recurring annual expense assuming one reportable event per month is $600 [24 hours x $25/hour] per facility.

Based on the above assumptions, the average first year expense is $1,100 [$500 start-up costs plus $600 recurring expenses] per facility. The average expense for subsequent years is $600 per facility. The cost to all affected entities after year one is approximately $126,400 annually [44 hospitals x $600].

The costs associated with the rule are necessary based on Executive Order 05-10, which requires the ISDH to establish a medical errors reporting system. The IEDC does not object to the fiscal impact associated with the proposed rule. The requirements imposed under the proposed rule will support improvements to the level of healthcare provided in Indiana. Facilities can reduce the cost associated with compliance with this rule by taking steps to reduce the number of serious adverse events occurring in their facility

If you have any questions about the comments contained herein please contact me at 232-8962 or rasberry@iedc.in.gov.

Regards,

Ryan Asberry
Director – Research
Indiana Economic Development Corporation